



## Complete Summary

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### GUIDELINE TITLE

ACR Appropriateness Criteria™ for percutaneous biliary drainage in malignant biliary obstruction.

### BIBLIOGRAPHIC SOURCE(S)

Van Moore A, Levy JM, Duszak RL, Akins EW, Bakal CW, Denny DF, Martin LG, Pentecost MJ, Roberts AC, Vogelzang RL, Kent KC, Perler BA, Resnick MI, Richie J, Dawson S. Percutaneous biliary drainage in malignant biliary obstruction. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun; 215(Suppl): 1055-66. [29 references]

## COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis

RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

## SCOPE

### DISEASE/CONDITION(S)

Malignant biliary obstruction

### GUIDELINE CATEGORY

Treatment

### CLINICAL SPECIALTY

Gastroenterology

Oncology

Radiology

### INTENDED USERS

Health Plans  
Hospitals  
Managed Care Organizations  
Physicians  
Utilization Management

#### GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of percutaneous biliary drainage in the treatment of malignant biliary obstruction

#### TARGET POPULATION

Patients with malignant biliary obstruction

#### INTERVENTIONS AND PRACTICES CONSIDERED

Percutaneous biliary drainage

#### MAJOR OUTCOMES CONSIDERED

- Utility of percutaneous biliary drainage in the treatment of malignant biliary obstruction
- Morbidity or mortality associated with malignant biliary obstruction
- Improved care (especially palliative care)
- Quality of life

### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of recent peer-reviewed medical journals, primarily using the National Library of Medicine's MEDLINE database. The developer identified and collected the major applicable articles.

#### NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

#### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)  
Weighting According to a Rating Scheme (Scheme Not Given)

## RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

## METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

## DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

## DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed to reach agreement in the formulation of the Appropriateness Criteria. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by the participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty (80) percent agreement is considered a consensus. If consensus cannot be reached by this method, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

## COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

## METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria and the Chair of the American College of Radiology Board of Chancellors.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria™

Interventional Procedure: Percutaneous Transhepatic Biliary Drainage—  
Right Sided Approach

Variant 1: Jaundiced patient, no evidence of metastasis, normal liver.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
<ul style="list-style-type: none"><li>Intractable pruritis</li></ul>	8	
<ul style="list-style-type: none"><li>Failed endoscopic retrograde cholangiopancreatography (ERCP)</li></ul>	7	
<ul style="list-style-type: none"><li>Over 70 years old</li></ul>	7	
<ul style="list-style-type: none"><li>Pruritis controlled with medication</li></ul>	3	
<ul style="list-style-type: none"><li>No ERCP attempted</li></ul>	3	
Physical Examination		
<ul style="list-style-type: none"><li>Febrile, appears septic</li></ul>	8	
<ul style="list-style-type: none"><li>Gross ascites</li></ul>	3	
Laboratory Findings		

• Bilirubin <10 mgm%	8	
• Bilirubin >10 mgm %	8	
• Elevated white blood cell (WBC) count	8	
• Correctable coagulopathy	7	
• Biopsy-proven malignant disease	7	
• No biopsy diagnosis	6	
• Bilirubin <4 mgm %	3	
• Uncorrectable coagulopathy	2	
Imaging Findings		
• No clear mass by computed tomography/ultrasound/magnetic resonance imaging (CT/US/MRI)	8	
• Ampullary mass, no pancreatic mass	7	
• Pancreatic head mass	7	
• Peripancreatic lymphadenopathy	7	
• Prominent biliary tree dilation	7	
• Mild ascites	6	
• No evidence of dilated biliary	3	

tree		
<p align="center"><u>Appropriateness Criteria Scale</u></p> <p align="center">1 2 3 4 5 6 7 8 9</p> <p align="center">1=Least appropriate 9=Most appropriate</p>		

Variant 2: Jaundiced patient, local metastatic disease, normal liver.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Intractable pruritis	8	
• Failed ERCP	7	
• Over 70 years old	7	
• Pruritis controlled with medication	4	
• No ERCP attempted	3	
Physical Examination		
• Febrile, appears septic	8	
• Gross ascites	3	
Laboratory Findings		
• Bilirubin >10 mgm%	8	
• Elevated WBC count	8	

• Bilirubin <10 mgm %	7	
• Correctable coagulopathy	7	
• No biopsy diagnosis	7	
• Biopsy-proven malignant disease	7	
• Bilirubin <4 mgm %	3	
• Uncorrectable coagulopathy	2	
Imaging Findings		
• No clear mass by CT/US/MRI	7	
• Ampullary mass, no pancreatic mass	7	
• Pancreatic head mass	7	
• Peripancreatic lymphadenopathy	7	
• Prominent biliary tree dilation	7	
• Regional lymphatic spread	7	
• Mild ascites	6	
• No evidence of dilated biliary tree	3	
• Hepatic metastasis in drainage path	No Consensus	

<u>Appropriateness Criteria Scale</u>		
1 2 3 4 5 6 7 8 9		
1=Least appropriate 9=Most appropriate		

Variant 3: Jaundiced patient, widespread metastatic disease, normal liver.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Intractable pruritis	8	
• Failed ERCP	7	
• Pruritis controlled with medication	3	
• No ERCP attempted	3	
Physical Examination		
• Febrile, appears septic	8	
• Gross ascites	3	
Laboratory Findings		
• Bilirubin >10 mgm%	7	
• Correctable coagulopathy	7	
• Biopsy-proven malignant disease	7	
• Elevated WBC count	7	



• No biopsy diagnosis	6	
• Bilirubin <4 mgm %	3	
• Uncorrectable coagulopathy	2	
• Bilirubin <10 mgm %	No Consensus	
Imaging Findings		
• No clear mass by CT/US/MRI	7	
• Ampullary mass, no pancreatic mass	7	
• Pancreatic head mass	7	
• Peripancreatic lymphadenopathy	7	
• Prominent biliary tree dilation	7	
• Regional lymphatic spread	7	
• Mild ascites	5	
• No evidence of dilated biliary tree	3	
• Hepatic metastasis in drainage path	No Consensus	
<p align="center"><u>Appropriateness Criteria Scale</u></p> <p align="center">1 2 3 4 5 6 7 8 9</p> <p align="center">1=Least appropriate 9=Most appropriate</p>		

Variant 4: Jaundiced patient, metastasis to right lobe.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Intractable pruritis	8	
• Failed ERCP	7	
• No significant portal hypertension	7	
• Mild portal hypertension	7	
• Over 70 years old	7	
• Severe portal hypertension	4	
• No ERCP attempted	3	
• Pruritis controlled with medication	3	
Physical Examination		
• Febrile, appears septic	8	
• Gross ascites	3	
Laboratory Findings		
• Elevated WBC count	8	
Imaging Findings		
• No clear mass by CT/US/MRI	7	

• Ampullary mass, no pancreatic mass	7	
• Pancreatic head mass	7	
• Peripancreatic lymphadenopathy	7	
• Mild ascites	7	
• Prominent biliary tree dilation	7	
• Metastatic lesion in right lobe drainage path	7	
• Gross ascites around liver	3	
• No evidence of dilated biliary tree	3	
<p align="center"><u>Appropriateness Criteria Scale</u></p> <p align="center">1 2 3 4 5 6 7 8 9</p> <p align="center">1=Least appropriate 9=Most appropriate</p>		

Variant 5: Jaundiced patient, no evidence of metastasis, cirrhotic liver.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Intractable pruritis	8	
• Failed ERCP	7	
• No significant portal hypertension	7	

• Over 70 years old	7	
• Mild portal hypertension	5	
• Severe portal hypertension	4	
• No ERCP attempted	3	
• Pruritis controlled with medication	3	
Physical Examination		
• Febrile, appears septic	8	
• Gross ascites	3	
Laboratory Findings		
• Bilirubin >10 mgm %	8	
• Elevated WBC count	8	
• Correctable coagulopathy	7	
• Biopsy-proven malignant disease	7	
• Bilirubin <10 mgm %	6	
• Bilirubin <4 mgm %	3	
• Uncorrectable coagulopathy	2	
• No biopsy diagnosis	No Consensus	

Imaging Findings		
• No clear mass by CT/US/MRI	7	
• Ampullary mass, no pancreatic mass	7	
• Pancreatic head mass	7	
• Peripancreatic lymphadenopathy	7	
• Prominent biliary tree dilation	7	
• Mild ascites	6	
• No evidence of dilated biliary tree	3	
<p align="center"><u>Appropriateness Criteria Scale</u></p> <p align="center">1 2 3 4 5 6 7 8 9</p> <p align="center">1=Least appropriate 9=Most appropriate</p>		

Variant 6: Jaundiced patient, local metastatic disease, cirrhotic liver.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Intractable pruritis	8	
• Failed ERCP	7	
• No significant portal hypertension	7	

• Over 70 years old	7	
• Mild portal hypertension	6	
• Pruritis controlled with medication	4	
• Severe portal hypertension	4	
• No ERCP attempted	3	
Physical Examination		
• Febrile, appears septic	8	
• Gross ascites	2	
Laboratory Findings		
• Bilirubin >10 mgm %	8	
• Correctable coagulopathy	8	
• No biopsy diagnosis	7	
• Biopsy-proven malignant disease	7	
• Elevated WBC count	7	
• Bilirubin <10 mgm %	6	
• Bilirubin <4 mgm %	3	
• Uncorrectable coagulopathy	2	

Imaging Findings		
• No clear mass by CT/US/MRI	7	
• Ampullary mass, no pancreatic mass	7	
• Pancreatic head mass	7	
• Peripancreatic lymphadenopathy	7	
• Prominent biliary tree dilation	7	
• Regional lymphatic spread	7	
• Mild ascites	5	
• No evidence of dilated biliary tree	3	
• Hepatic metastasis in drainage path	3	
<p align="center"><u>Appropriateness Criteria Scale</u></p> <p align="center">1 2 3 4 5 6 7 8 9</p> <p align="center">1=Least appropriate 9=Most appropriate</p>		

Variant 7: Jaundiced patient, wide spread metastatic disease, cirrhotic liver.

Presentation/Signs/Symptoms	Appropriateness Rating	Comments
History		
• Intractable pruritis	7	

• Failed ERCP	6	
• Mild portal hypertension	5	
• No ERCP attempted	2	
• Severe portal hypertension	2	
• Pruritis controlled with medication	2	
• No significant portal hypertension	No Consensus	
Physical Examination		
• Febrile, appears septic	6	
• Gross ascites	2	
Laboratory Findings		
• Bilirubin <10 mgm%	6	
• Bilirubin >10 mgm %	6	
• Correctable coagulopathy	6	
• Elevated WBC count	6	
• Uncorrectable coagulopathy	2	
• Bilirubin <4 mgm %	2	
• No biopsy diagnosis	No Consensus	



• Biopsy-proven malignant disease	No Consensus	
Imaging Findings		
• Prominent biliary tree dilation	6	
• Ampullary mass, no pancreatic mass	5	
• Pancreatic head mass	5	
• Peripancreatic lymphadenopathy	5	
• No evidence of dilated biliary tree	2	
• Mild ascites	No Consensus	
• No clear mass by CT/US/MRI	No Consensus	
• Regional lymphatic spread	No Consensus	
• Hepatic metastasis in drainage path	No Consensus	
<p align="center"><u>Appropriateness Criteria Scale</u></p> <p align="center">1 2 3 4 5 6 7 8 9</p> <p align="center">1=Least appropriate 9=Most appropriate</p>		

## Summary

Percutaneous transhepatic biliary drainage and subsequent stenting for malignant biliary obstruction has evolved considerably over the last 15 years. The parallel, but more recent, developments in endoscopic techniques have changed the role of interventional radiologic management of the patient with malignant biliary obstruction and these roles are likely to continue to evolve. One constant factor in the decision of how to treat these patients is the fact that the large majority of

patients with malignant biliary obstruction are surgically unresectable. At this time, radiologic drainage and stenting is the procedure of choice for unresectable obstruction of the distal common duct when endoscopic techniques have failed or are not available, and is the preferred procedure for hilar level obstructions.

#### CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

As a treatment for malignant biliary obstruction, percutaneous biliary drainage has been used for preoperative staging and to provide palliation of symptoms and improvement in quality of life.

#### POTENTIAL HARMS

Cholangitis is the major complication of percutaneous biliary drainage, and is seen in up to 47% of patients who undergo the procedure. Other complications that are seen with biliary drainage include significant hemorrhage (3% to 7%), sepsis (3% to 5%), pericatheter leakage (15% to 20%), catheter dislodgment (10% to 20%), and pleural transgression (1% to 5%). Patients who are unable to have internal biliary drainage and who are treated with long-term external catheter drainage run a significant risk of hyponatremia and low bicarbonate levels from the loss of bile constituents. Prolonged catheter drainage also results in depletion of the bile salts, but this complication is less frequently seen now that modern catheters and guidewires allow internal biliary drainage in nearly all patients. Periprocedural mortality rates related to the biliary drainage have been reported from 0.7% to 8.6%.

### QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those

exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Van Moore A, Levy JM, Duszak RL, Akins EW, Bakal CW, Denny DF, Martin LG, Pentecost MJ, Roberts AC, Vogelzang RL, Kent KC, Perler BA, Resnick MI, Richie J, Dawson S. Percutaneous biliary drainage in malignant biliary obstruction. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):1055-66. [29 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

1996 (revised 1999)

### GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

#### SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these American College of Radiology Appropriateness Criteria™.

#### GUIDELINE COMMITTEE

American College of Radiology Appropriateness Criteria™ Committee, Expert Panel on Interventional Radiology.

#### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Arl Van Moore, Jr., MD; Jonathan M. Levy, MD; Richard L. Duszak, Jr., MD; E. William Akins, MD; Curtis W. Bakal, MD; Donald F. Denny, Jr., MD; Louis G. Martin, MD; Michael J. Pentecost, MD; Anne C. Roberts, MD; Robert L. Vogelzang, MD; K. Craig Kent, MD; Bruce A. Perler, MD; Martin I. Resnick, MD; Jerome Richie, MD; Steven Dawson, MD

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### GUIDELINE STATUS

This is the current release of the guideline. It is a revision of a previously issued version (Appropriateness criteria for percutaneous biliary drainage in malignant biliary obstruction. Reston [VA]: American College of Radiology [ACR]; 1996. 12 p.).

An update is not in progress at this time.

The American College of Radiology Appropriateness Criteria™ are reviewed after five years, if not sooner, depending upon introduction of new and highly significant scientific evidence. The next review date for this topic is 2004.

#### GUIDELINE AVAILABILITY

Electronic copies: Available (in Portable Document Format [PDF]) from the [American College of Radiology \(ACR\)](#).

Print copies: Available from ACR, 1891 Preston White Drive, Reston, VA 20191.  
Telephone: (703) 648-8900.

#### AVAILABILITY OF COMPANION DOCUMENTS

None available

#### PATIENT RESOURCES

None available

#### NGC STATUS

This summary was completed by ECRI on March 28, 2002. The information was verified by the guideline developer on May 28, 2002.

#### COPYRIGHT STATEMENT

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